Tokyo Boeki Medical System Ltd.
3-63, 2-chome Ninomiyahigashi Akiruno-shi Tokyo 197-0815 Japan
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510(k) SUMMARY

Submitter's Name/Address

Submitter's Name:	Tokyo Boeki Medical System Ltd.
Submitter's Address:	3-63, 2-chome Ninomiyahigashi Akiruno-shi Tokyo 197-0815 Japan
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Owner/Operator Number:	9060135

Contact Person (United States Agent)

Name of Agent:	James M. Clinton
Agent's Business Name:	Quality and Regulatory Consulting, LLC
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Date of Preparation of this Summary: November 5, 2004

Device Trade or Proprietary Name : Prestige 24i, Sirrus, MGC 240
(These are the same models except the names.
For convenience of explanation, the Prestige 24i is represented of the three in this summary.)

Device Common Name: Clinical Chemistry Analyzer
(with optional ISE Module)

Classification Numbers/Class:

75JJE,	Class I
75JGS,	Class II
75CEM,	Class II
75CGZ,	Class II
75JIX	Class II

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K040958

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510(k) Summary:

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(K) number is : K040958.

Description:

The Prestige 24i with Ion-Selective Elective module additionally measures the concentration of the electrolytes, sodium, potassium and chloride in samples, using indirect potentiometry.

Substantial Equivalence:

Substantial equivalence has been demonstrated between the Roche Cobas Mira Plus (K851172) and the Prestige 24i. Both analyzers are used to analyze for electrolytes. Both analyzers are calibrated with known concentration calibrator material and both utilize Ion-Selective Electrodes.

Intended Use:

This device with an optional Ion-Selective Electrode (ISE) module is a clinical chemistry analyzer intended to be used for the measurement of sodium, potassium and chloride in samples.

Performance Characteristics:

A correlation analysis between Roche Cobas Mira Plus and the Prestige 24i yielded the following results :

Representative Method		Correlation Coefficient	Slope (Least-Squares)	Y-axis intercept
1	Sodium	0.97	0.95	+6.8625 mmol/L
2	Potassium	0.99	0.98	- 0.0135 mmol/L
3	Chloride	0.98	0.97	+3.2579 mmol/L

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The linearity test yielded the following results:

Representative Method	**Linearity**
Sodium	70 - 200 mmol/L (Serum)
Potassium	1 - 50 mmol/L (Serum)
Chloride	70 - 200 mmol/L (Serum)

The precision test results:

		Item	Sample 1 %CV	Sample 2 %CV
4	Within Run N=20	Sodium	1.0	0.6
		Potassium	1.7	1.0
		Chloride	0.5	0.8
5	Day by Day-Run N=20	Sodium	1.4	1.3
		Potassium	1.5	1.3
		Chloride	2.5	2.3

Conclusion:

The data demonstrates that Prestige 24i is substantially equivalent to the Roche Cobas Mira (K851172).

DEPARTMENT OF HEALTH & HUMAN SERVICES

FEB 15 2005

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Tokyo Boeki Medical System LTD.
c/o Mr. James M. Clinton
United States Agent
Quality & Regulatory Consulting, LLC
5304 Golden Moss Trail
Raleigh, NC 27613-5662

Re: k040958
Trade/Device Name: Prestige models 24i and 400 and MGC model 240
Regulation Number: 21 CFR 862.1600
Regulation Name: Potassium Test System
Regulatory Class: Class II
Product Code: CEM, CGZ, JGS, JIX, JJE
Dated: January 28, 2005
Received: January 31, 2005

Dear Mr. Clinton:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (240)276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Jean M. Cooper MS, DVM

Jean M. Cooper, MS, D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known) K040958

Device Name: Prestige 24i; Sirrus; MGC 240 (three identical models varying in name only)

Indications For Use: This device with an optional Ion Selective Electrode (ISE) module is a clinical chemistry analyzer intended to be used for the measurement of sodium, potassium and chloride in serum to monitor electrolyte balance.

Prescription Use ___Yes___ AND/OR Over-The-Counter Use ___No___
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K040958